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August 14, 2001

Kimberly Topper
Food and Drug Administration
CDER Advisors and Consultants Staff
HFD-21
5600 Fisher's Lane
Rockville, MD 20857

RE: Letter for Life Support and Drug Meeting
DOCKET #: 01N-0256

Dear Ms. Topper:

I am writing to add my voice and opinion to the evolving debate over the appropriate use of opioid based analgesics in the treatment of chronic, non-cancer pain. By way of brief introduction, I am a clinical neurologist having been in practice for 20 years. My present work duties include evaluating and treating individuals with chronic, non-cancer pain. This involves many different areas including the realm of headache, peripheral nerve injury, chronic arthritic conditions and failed spinal surgery patients.

Over my 20 years in practice, I have come to realize that the philosophy of treatment pertaining to chronic, non-cancer pain patients has changed to at least some degree. Use of effective analgesia in properly selected patients is considered the appropriate standard of care by many health care providers. In my opinion, the key to appropriate and adequate treatment is thorough clinical evaluation leading to appropriate patient selection. In the realm of chronic pain, in addition to multiple medical conditions for which there is no curative treatment, there are co-morbid complicating factors which challenge the skill of the clinician. This includes psychological and socioeconomic factors which may promote pain and in some instances be the principal factor involved. In my opinion, it is the appropriate role of the clinician to make accurate judgments in this regard to sort through the different categories as best as may be done to differentiate between patients with a primarily organic process, patients with a primarily psychological process and patients with a mixed picture. For those who have a primarily organic process for which there is no curative treatment and pain management is significant and functionally

limiting, I have found the use of long acting opioid analgesics to be highly effective. I do not on the other hand believe that these should be used freely or without discretion and individuals who fall into categories in which psychological and socioeconomic factors are predominant would best be treated with other modalities and agents.

It is with great concern that I have read of the increasing controversy pertaining to OxyContin and similar agents in the management of chronic pain. It is my belief that if this medication comes under severe restriction, three problems will emerge. First, the problem of drug abuse in America will not have been solved. Second, there is no clear cut substitute which may lead to increased use of medications which have appreciably higher abuse potentials and limited, if any, efficacy in the treatment of non-cancer pain such as Hydrocodone in its many forms. Finally, many legitimate and innocent patients will suffer unnecessarily.

Sincerely,

Reginald J. Rutherford, M.D., FRCP(C)

RJR:alc